European Directorate for the Quality of Medicines & HealthCare | Direction européenne de la qualité du médicament & soins de santé

COUNCIL OF EUROPE
CONSEIL DE L'EUROPE

Certification of Substances Department

Certificate of suitability
No. R0-CEP 2020-415-Rev 00

Name of the substance:
DOBUTAMINE HYDROCHLORIDE

Name of holder:
HAINAN POLY PHARMACEUTICAL COMPANY LIMITED
Guilinyang Economic Development Area
Meilan District
China-571 127 Haikou, Hainan Province

Site(s) of production:
SEE ANNEX 1

After examination of the information provided on the manufacturing method and subsequent processes (including purification) for this substance on the site(s) of production listed in annex, we certify that the quality of the substance is suitably controlled by the current version of the monograph **DOBUTAMINE HYDROCHLORIDE** no. 1200 of the European Pharmacopoeia, current edition including supplements.

In the last steps of the synthesis water is used as solvent.

A risk management summary for elemental impurities has been provided. (Annex 2)

The re-test period of the substance is 24 months if stored in double laminated film bags (polyethylene terephthalate /aluminium /polyethylene), placed in a fibre drum.

The holder of the certificate has declared the absence of use of material of human or animal origin in the manufacture of the substance.

The submitted dossier must be updated after any significant change that may alter the quality, safety or efficacy of the substance.

Manufacture of the substance shall take place in accordance with the Good Manufacturing Practice and in accordance with the dossier submitted.

Failure to comply with these provisions will render this certificate void.

Address: 7 Allée Kastner, CS 30026
F-67081 Strasbourg (France)
Tel: +33 (0) 3 88 41 30 30 – Fax: +33 (0) 3 88 41 27 71 - e-mail: cep@edqm.eu
Internet: http://www.edqm.eu

This certificate is granted within the framework of the procedure established by the European Pharmacopoeia Commission [Resolution AP-CSP (07) 1] for a period of five years starting from **22 September 2021**. Moreover, it is granted according to the provisions of Directive 2001/83/EC and Directive 2001/82/EC and any subsequent amendment, and the related guidelines.

This certificate has two annexes of 1 page each.
This certificate has:
lines.

On behalf of the
Director of EDQM

Strasbourg, 22 September 2021

DECLARATION OF ACCESS *(to be filled in by the certificate holder under their own responsibility)*

HAINAN POLY PHARMACEUTICAL COMPANY LIMITED, as holder of the certificate of suitability

R0-CEP 2020-415-Rev 00 for Dobutamine hydrochloride

hereby authorises .....
(*name of the pharmaceutical company*)

to use the above-mentioned certificate of suitability in support of their application(s) for the following Marketing Authorisation(s): (*name of product(s) and marketing number(s), if known*)

The holder also certifies that no significant changes to the operations as described in the CEP dossier have been made since the granting of this version of the certificate.

Date and Signature (*of the CEP holder*):

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Annex 1: Site(s) of production for R0-CEP 2020-415-Rev 00

Production of Dobutamine hydrochloride:
HAINAN POLY PHARMACEUTICAL COMPANY LIMITED
Guilinyang Economic Development Area
Meilan District
China-571 127 Haikou, Hainan Province

Risk Assessment Results of Elemental Impurities in Dobutamine hydrochloride

Intended route of administration / Use of the substance: Parenteral				
Element	**Class**	**Intentionally added?**	**Considered in risk management?**	**Conclusion**
Cd	1	No	Yes	Absent
Pb	1	No	Yes	Absent
As	1	No	Yes	Absent
Hg	1	No	Yes	Absent
Co	2A	No	Yes	Absent
V	2A	No	Yes	Absent
Ni	2A	No	Yes	Absent
Tl	2B	No	No	N/A
Au	2B	No	No	N/A
Pd	2B	No	No	N/A
Ir	2B	No	No	N/A
Os	2B	No	No	N/A
Rh	2B	No	No	N/A
Ru	2B	No	No	N/A
Se	2B	No	No	N/A
Ag	2B	No	No	N/A
Pt	2B	No	No	N/A
Li	3	No	Yes	Absent
Sb	3	No	Yes	Absent
Ba	3	No	No	N/A
Mo	3	No	Yes	Absent
Cu	3	No	Yes	Absent
Sn	3	No	Yes	Absent
Cr	3	No	Yes	Absent

**Absent: less than 30% ICH Q3D Option 1 limit.*